MINUTES FROM THE EPA SCIENCE ADVISORY BOARD
Drinking Water Committee
Telephone Conference Meeting
June 11, 2002

PURPOSE: The Drinking Water Committee (DWC) of the EPA Science Advisory Board (SAB) met via telephone conference on June 11, 2002 to plan for how it might respond to the Agency's request to review two regulatory proposals, 1) the Six Year Review - Notice of Intent on Preliminary Revise/Not Revise Decisions for Existing Drinking Water Standards and 2) the Contaminant Candidate List 1 Notice of Intent of Regulatory Determinations. Additionally, members were updated on the Agency progress on CCL 2. The Comprehensive Drinking Water Research Strategy was also mentioned as a Fiscal Year 2003 review item. Attachment A is the Federal Register notice announcing the meeting (FR Vol. 67, No. 101, Page 36593, May 24, 2002). The meeting was not held to conduct the actual reviews. An agenda is included as Attachment B.

LOCATION: The meeting was coordinated from room 6013 Ariel Rios Building, US EPA, 1200 Pennsylvania Ave., NW, Washington, DC.

PARTICIPANTS: The following participated in this meeting: Drs. Rhodes Trussell, David Baker, Mary Davis, Ricardo DeLeon, Sidney Green, Barbara Harper, Irva Hertz-Picciotto, LD McMullen, Christine Moe, Philip Singer, and Gary Toranzos. A committee roster is included as Attachment C and a set of biographical sketches is included as Attachment D. EPA Staff and persons from the public who participated in or observed the meeting are indicated on the log sheets (Attachment E).

MEETING SUMMARY: A summary of the Committee's activities follows.

1. CONVENE THE MEETING

Mr. Miller logged participants and observers into the call.

Dr. Trussell welcomed members, the agency and the public to the meeting and discussed some of the history of the DWC - EPA interactions that reflect a transition in how their interactions have evolved over time and how they will need to continue to change because of new SAB requirements for panel development. He noted that, in recent years, the working relationship between the SAB and the EPA OGWDW has become somewhat awkward. The 1986 SDWA requires that National Primary Drinking Water Regulations (NPDWRs) be sent to the Science Advisory Board (SAB) for comment before they are formally proposed. As a matter of US Government Policy, regulatory proposals are considered deliberative in nature and not public until they are released by the Office of Management and Budget (OMB). On the other hand, the SAB is a FACA Committee requiring that all advisory committee actions be open to public scrutiny. However, for deliberative documents FACA defers to the Freedom of

Information Act (FOIA-Section 552 Title 5, US Code) in its requirements for public inspection of committee review materials, and in that regard, FOIA provides an exemption from the requirement for public release that applies to deliberative documents. Notwithstanding, regulatory proposals are provided to the Committee for review late in the cycle when they are primarily legal in nature (not purely science). Thus, not only is sufficient time for review not available, but the ability of the EPA to respond to any scientific advice is extremely limited. Dr. Trussell noted that the SAB understands that the Agency has good reasons for operating in this manner and that his comments are not intended to criticize EPA behavior. Rather, they are intended to highlight the need for EPA and the SAB to explore new ways to work together to meet the mandates of the Act and to deliver timely science advice to the Administrator.

Dr. Trussell noted that the purpose of the phone call was to plan for how the Committee might respond to the EPA request to look at preliminary notices of intent on both the Six-Year Review of NPDWRs (6-Year Review) and Contaminant Candidate List 1 (CCL 1) regulatory determinations. He noted that this meeting would not be a review meeting to deliver advice to the Administrator. Such a review would come later and as part of the process of preparing for the meeting the SAB would decide whether additional expertise would be needed to supplement the DWC.

Mr. Miller made a series of introductory comments about the type of meeting and COI implications. He noted that:

a. this is a meeting of the EPA SAB DWC members;
b. the meeting is for planning purposes to consider a number of specific issues that will be on the DWC agenda for the immediate future;
c. the meeting is not for the purpose of conducting a review and thus it does not constitute a deliberation, decision or action to develop advice to the Administrator and therefore, the issue does not constitute a Particular Matter (PM),
d. because this is not a PM, Conflict of Interest and Appearances are not an issue

Mr. Miller further stated that any review meetings on issues discussed at this planning meeting will be staffed with panelists using the newly approved guidance from the SAB Executive Committee.

Mr. Miller then asked the DWC members to introduce themselves noting their names, titles, and affiliations only. He noted that biographical sketches of members are on the SAB website and also available in paper copy at the meeting room itself for persons wishing to know more about the DWC members involved in this meeting.

The members introduced themselves.

2. SIX-YEAR REVIEW - NOTICE OF INTENT PRELIMINARY REVISE/NOT REVISE DECISION FOR EXISTING DRINKING WATER STANDARDS

Mr. James Taft, Office of Ground Water and Drinking Water introduced the topic and two staff members, Ms. Judy Lebowich and Ms. Wynne Miller, who would conduct the briefing. Mr. Taft noted that neither of the topics for the day's agenda were "proposed rules" under the meaning of SDWA. They are preliminary decision that are released to the public for comment at this time. Final decisions would, if in the affirmative for any contaminant, would initiate a rule-making process. He stated that the process used in evaluating 69 pre-1996 NPDWRs was built upon comments provided to EPA by the National Drinking Water Advisory Council (NDWAC). Further, the review has made use of inputs from a number of relevant EPA offices in addition to OW.

Mr. Taft indicated that there are three ways for contaminants to get onto the active agenda for consideration by EPA. One is to be included as a specific mandate in SDWA (e.g., arsenic), two is to be listed on a CCL – the new way that contaminants will enter the system in the future, and third is to be a part of the 6-Year Reviews that consider the need to revise existing standards.

For the 6-Year Review, SDWA specifies at Section 1412(b)(9) that: "the Administrator shall, not less often than every 6 years, review and revise, as appropriate, each primary drinking water regulation...any revision shall maintain, or provide for greater, protection of the health of persons."

Ms. Judy Lebowich noted the objectives of the 6-Year Review to be to: 1) develop a systematic protocol to review NPDWRs and to determine if there is a basis for considering revision; 2) review 69 pre-1996 NPDWRs; and to 3) publish a notice of intent describing the protocol and preliminary revise/not revise decisions.

Ms. Lebowich stated that the Protocol has the following elements:

a) Health Effects: Identification of potential changes that may affect the Maximum Contaminant Level Goal (MCLG).

b) Analytical Methods: Identify potential changes/limits in feasibility if the MCL is now limited by practical quantitation levels (PQL) or if the MCLG/MCL might decrease.

c) Treatment Technology: Evaluate the feasibility if potential changes in the MCLG/MCL or if there is an indication that best available technology (BAT)/treatment techniques (TT) need review.

d) Other Regulatory Requirements: Identify non MCLG/MCL or non-TT changes that have not been addressed alternatively.

e) Occurrence and Exposure: Evaluate when a potential change in health or technology might be the case.

i) based on 16-state database.

f) Economic Considerations: Considers available economic information when health or technical reasons exist for changing an NPDWR. At this stage it is not a detailed analysis.

In terms of the operation of the protocol, the Agency:

a) Considers HEALTH EFFECTS:

i) If a risk assessment is underway/planned the determination is for NO REVISION AT THIS TIME

ii) If data suggest a possible MCLG change EPA CONSIDERS TECHNICAL FEASIBILITY(analytical and treatment) and if OTHER REGULATORY REVISIONS are appropriate

iii) If data do not suggest a possible MCLG change EPA considers whether OTHER REGULATORY REVISIONS are appropriate

iv) If data suggest there is no health basis for revision NO REVISION AT THIS TIME is determined

b) ANALYTICAL METHODS:

i) If health data suggest a possible MCLG change CONSIDER if analytical feasibility is a limitation/still a limitation.

ii) If MCL is limited by analytical feasibility CONSIDER if analytical feasibility is a limitation/still a limitation.

iii) If data suggest there is no analytical feasibility basis for revision NO REVISION AT THIS TIME is determined

c) TREATMENT TECHNOLOGY:

i) If health data suggest a possible MCLG change CONSIDER if Treatment technology feasibility is a limitation/still a limitation.

ii) If MCL is limited by treatment technology feasibility CONSIDER if treatment technology feasibility is a limitation/still a limitation.

iii) If data suggest there is no treatment technology feasibility basis for revision NO REVISION AT THIS TIME is determined

d) OTHER REGULATORY REVISIONS:

i) For all Contaminants, CONSIDER IF OTHER REGULATORY REVISIONS are appropriate;

ii) If data suggest there is no other regulatory revision appropriate, NO REVISION AT THIS TIME is determined

e) OCCURRENCE AND EXPOSURE:

i) If no Health, Analytical, or Treatment bases exist for a revision, then NO REVISION AT THIS TIME is determined

ii) If a Health, Analytical, or Treatment basis exists for a revision, then CONSIDER OCCURRENCE AND EXPOSURE

iii) If a SIGNIFICANT GAIN IN PUBLIC HEALTH PROTECTION exists, CONSIDER DATA ADEQUACY

iv) If no SIGNIFICANT GAIN IN PUBLIC HEALTH PROTECTION then NO REVISION AT THIS TIME IS determined

f) ECONOMIC CONSIDERATIONS:

i) If a SIGNIFICANT GAIN IN COST SAVINGS exists, CONSIDER DATA ADEQUACY

ii) If no SIGNIFICANT GAIN IN COST SAVINGS exists then NO REVISION AT THIS TIME IS determined

g) DATA SUFFICIENCY:

i) If data are not sufficient to support regulatory revision DETERMINE DATA GAPS OR RESEARCH NEEDS and NO REVISION AT THIS TIME is determined

ii) If data are sufficient to support regulatory revision then the contaminant is A CANDIDATE FOR REVISION OF ITS NPDWR

Ms. Wynne Miller stated that "not revise" decisions are on a "for now" basis. They are not cast in concrete for all time. They can at least be revisited at the next six year review. If new important data comes to light a contaminant can be considered "off cycle." A decision to "revise" would be the start of regulatory development processes that would implement specific detailed analyses of many factors.

The OW representatives then discussed in detail the outcome of the 6-Year Review for the existing 69 contaminants by the following groups:

a) No revision at this time; updates to risk assessment underway – 36 contaminants

Many are undergoing updates to their risk assessments in other agency programs [(ORD, 16), (OPP, 11), (OW, 4), (OPPT, 1), (OSW, 1), and (Region 8, 1)]. Many are due in 2002-3. Three, cyanide, di(ethyl-hexyl)adipate, and thallium, have new data.

b) No revision at this time; NPDWR remains appropriate – 17 contaminants

No information identified to provide a health or technical basis to change current requirements (based on MCLG, MCL, TT, other regulatory provision consideration)

c) No revision at this time; negligible gain from revision – 12 contaminants

Revision could occur, however, the gain in health protection or cost savings would

be negligible.

d) No revision at this time; data gaps – 3 contaminants
New information that may affect the MCLG or MCL exists; however, data gaps exist that must be resolved.

e) Revise – 1 'contaminant'
Total Coliform Rule (TCR)

EPA will assess the effectiveness of the existing TCR in reducing public health risk; assess alternate/additional monitoring strategies for reducing the economic burden while maintaining or improving public health protection.

Revisions of the TCR may occur in a broader context and include consideration of Distribution System needs as well.

Ms Lebowich noted that the comment period for the preliminary NOI ends on June 17, 2002. EPA hopes to make final determinations early in 2003.

Members of the DWC had the following reactions/questions as a result of the Agency information provided on the 6-Year Review process:

a) How many of the risk assessments pending are in place;
b) How EPA determined the number of systems impacted when it considered occurrence and exposure issues;
c) The proportion of pre-1996 NPDWRs that are based on PQLs vs risk levels;
d) The manner in which EPA determined that a revision would impart only Negligible Gains in Public Health Protection even when thousands of people are potentially at risk; Criteria for such a "negligibility" determination should be clearly spelled out;
e) The existence of oral absorption or carcinogenicity data for chromium;
f) What EPA considered when it evaluated mode of action data for carcinogens;
g) The basis for continued interest in cancelled pesticides (persistence);
h) Though a good job is done on PQL discussion in the background, there are implications from privatization of monitoring sample programs that might make it difficult in the future to come up with data to support PQL determinations; a better discussion of how new methods will be approved would be helpful as well;
i) BAT discussions should do a better job of specifying characteristics that are a part of the technology;
j) Cross cutting issues need addressing: sensitive subpopulations, risk to children, mixtures and cumulative risk, waivers vs. consistency, paperwork reduction vs need for data, and how data adequacy determinations are made;
k) How to consider risk reduction with reproductive or developmental effects;
l) How appropriate are average values in surface water;
m) How well does the 16-State data represent the US spatially for specific contaminants?

How well are agricultural systems reflected in that data? Which is more important to the limitations in the data, resource availability or scientific progress?

n) Would the agency make the same decision on regulatory need if the 6-Year contaminants were evaluated through the CCL process?

Dr. Trussell asked what the Committee might do in response to EPA's request to comment on the 6-Year Review given that we could not respond to their request immediately. What expertise needs are there to conduct the review? Could the Committee look at the 6-Year Review protocol in relation to the first series of determinations as a way to evaluate what EPA did in its analysis?

a) Dr. Davis did not believe, even with all the information provided by EPA as background, that there is sufficient information to permit the DWC to answer the "consistency of protocol application" question in the charge.

b) Dr. Singer noted that EPA will implement the protocol again in 6 years. The DWC could consider the process, evaluate the logic behind the decisions made and suggest if the logic is appropriate.

Mr. Taft noted that the current action is a set of preliminary determinations and that the final action is for late this year or next. Considering the protocol is definitely on the table. The question would be which is more valuable, commenting on the decisions made on the first implementation of the 6-Year Review or making comments later on the protocol.

3. THE CONTAMINANT CANDIDATE LIST (CCL) 1 - FOR EXISTING DRINKING WATER STANDARDS - NOTICE OF INTENT OF REGULATORY DETERMINATIONS

Ms. Ann Codrington introduced the presenter for the CCL 1 Regulatory Determination topic. Due to the extra time spent on the first topic, the presentation on this topic had to be truncated somewhat.

Ms. Wirth stated that this is one of the processes discussed by Mr. Taft earlier when he enumerated the three ways in which contaminants come under active consideration for regulation by EPA. She noted that the SDWA requirements for CCL:

a) required a list of new contaminants to consider for regulation be developed (completed in March 1998);

b) that determinations to regulate 5 or more of these be made by August 2001 (missed the date);

c) that development of proposed regulations be completed within 24 months for those for which a determination to regulate is made.

Ms Wirth noted that a decision not to regulate is subject to judicial review. She also stated that the process is cyclical and repeats every five years. The next is due in February 2003.

EPA's analysis considered 3 items when it implemented its process which was recommended by NAS and NDWAC:

a) Health effects :
   i) evaluated the best available peer-reviewed studies and assessments
   ii) described adverse health effects and derived an "estimated health reference or benchmark level"
   iii) compared the 'benchmark' to occurrence information

b) Occurrence of a contaminant occurs in public water systems with a frequency and at levels of public health concern:
   i) collected, screened, and analyzed over 7 million analytical records
   ii) developed national occurrence and exposure estimates (how many systems/people are at, or near, the 'estimated health reference level')

c) Opportunity for Risk Reduction by determining if regulation would present a meaningful opportunity for health risk reduction.
   i) looked at alternative means for achieving risk reduction
   ii) considered geographic distribution (local vs national)
   iii) use and release information (has it been banned or has it been replaced, are trends increasing or decreasing)
   iv) other routes of exposure (in addition to drinking water)
   v) contributions from other sources (air, food)

Results of the analysis – EPA's recommended preliminary determinations for all nine contaminants was that "No regulatory action is appropriate." The conclusions from their analyses were:

a) *Acanthamoeba*: Lacks meaningful opportunity for health risk reduction

b) Aldrin: Low occurrence at levels of concern

c) Dieldrin: Low occurrence at levels of concern

d) Hexachlorobutadiene: Low occurrence at levels of concern

e) Manganese: Low adverse health effects

f) Metribuzin: Low occurrence at levels of concern

g) Naphthalene: Low occurrence at levels of concern

h) Sodium: Lacks meaningful opportunity for health risk reduction

i) Sulfate: Low adverse health effects

The next steps for CCL 1 include receipt and analysis of public comments, conducting a stakeholders' meeting, receipt of SAB comments, and preparing a notice of final determinations in late 2002.

In addition, Ms. Wirth noted that two remaining CCL 1 contaminants may be candidates for future "Off-Cycle" regulatory determination (perchlorate and metolachlor). Metolachlor is the second most widely used herbicide in the U.S. (primarily corn crops). Perchlorate is primarily associated with the manufacturing or testing of solid rocket fuels. It is also found in the manufacturing and detonation of fireworks and produced in large scale as a component of automobile air bags.

Members of the DWC had the following reactions/questions as a result of the Agency information provided on the CCL 1 presentation:

a) How is low levels of concern defined?

b) Is there a way in which EPA can target regulation to areas where larger numbers of people might be at risk, even though nationally, the numbers involved appear to be negligible? (Working with the states might be the most cost-effective way to go.)

c) Could a low concern be explained in terms of a risk being at a very low level of expected cases (e.g., one case in 50 years) even though the occurrence level might be greater than the standard?

4. CONSIDERATION OF ADDITIONAL BUSINESS - CCL 2

Mr. Thomas Carpenter, OGWDW, briefed the Committee on the current Agency thinking on its approach to meeting its requirement to publish CCL 2 by February 2003. He noted that the statutory requirements for CCL 2 are the same as CCL 1. The National Academy of Sciences (NAS) has provided recommendations on strategies for developing CCL 2. Their recommendations:

a) recommend a new, sophisticated classification approach that does not sacrifice complexity for transparency

i) allows for complex decision process that scores/weights classification attributes of contaminants based on pattern recognition (i.e., Neural Networks)
ii) could be applied to chemical and microbial contaminants
iii) calibrate and validate using existing NPDWR contaminants as training sets

b) recommends new molecular/genetic methods to identify new/emerging microbiological contaminants as part of the new approach

i) base evaluation of microbes on similarities of virulence, physical, and/or genetic attributes (Virulence Factor Activity Relationships)

aa) Indicators used by VFAR would include genetic elements, surface proteins, attachment factors, metabolic pathways, and other virulence attributes

bb) Output of VFAR would be a classification, outcomes, virulence, potency, and persistence.

ii) relies on new genomic and molecular analytical methods and indicators

iii) VFAR is long-term goal – need to identify interim products as proof of concept

aa) VFAR classifies pathogens, relies on molecular technologies and gene sequencing, requires additional research

EPA organized two workshops with NRC panel experts for OW staff on the "neural network and VFAR concepts. EPA developed approaches for phased implementation of the NRC recommendations. The NDWAC will be used as a stakeholder group to help make CCL 2 more transparent than CCL 1. NDWAC will, over the span of one year, have a workgroup to: "Discuss, evaluate, and provide advice on methodologies, activities, and analysis needed to implement the NRCs recommendations on an expanded approach for the CCL listing process.

5. ACTION

Dr. Trussell tasked himself and DWC Staff to work with Mr. Taft of the Office of Water to decide on a charge for a future DWC meeting on the 6-Year Review process (longer term comments on the protocol vs. nearer term comments on the first determinations). The CCL 1 project could also be conducted with the same intent subject to OW's desires.

The DWC will go forward with a review that is intended to be constructive and help EPA determine how it might need to change the process for its next implementation.

Additional consultation on the CCL 2 would be entertained by the Committee should the agency request.

Future efforts on these topics will take heed of the initial concerns that the Chair noted at the beginning of this meeting regarding the need for a new way to interact with the Agency on SDWA reviews.

A tentative date was set for a DWC review meeting on October 17-18, 2002. The charge, location, and panel composition are to be determined by consultation among the DWC Chair, members as appropriate, EPA OW representatives, and SAB staff.

3:45 pm Dr. Trussell adjourned the meeting.

I certify that these minutes are accurate to the best of my knowledge.

/ Signed /	**/ Signed /**
Dr. R. Rhodes Trussell	Mr. Thomas O. Miller
Chair	Designated Federal Officer
EPA SAB Drinking Water Committee	EPA SAB Drinking Water Committee

Attachments:

A FR Notice; Vol. 66, No. 217; 56557; November 8, 2001
B Panel Roster
C Panel Charge
D Panel Bios
E Sign in Sheets